

DEPARTMENT OF HEALTH AND HUMAN SERVICES

April, 4, 2000

Sally Van Wert, Ph.D.
Aventis CropScience
P.O. Box 12014
2 T. W. Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Van Wert:

This is in regard to Aventis' (formerly AgrEvoUSA) consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically modified MS6 "Male Sterile" corn (also known as SeedLink™). According to Aventis, this new line is modified for male sterility through the expression of the *barnase* gene from *Bacillus amyloliquefaciens* and for tolerance to glufosinate-ammonium through the expression of the *bar* gene from *Streptomyces hygroscopicus*.

As part of bringing the consultation regarding this product to closure, Aventis submitted a summary of its safety and nutritional assessment of the genetically modified MS6 male sterile corn on June 7, 1999, and submitted supplementary information on February 7, 2000. These communications informed the FDA of the steps taken by Aventis to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Aventis has conducted, it is our understanding that Aventis has concluded that corn silage and grains derived from the new variety are not materially different in composition, safety, and other relevant parameters from corn silage and grains currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0066. This file will be maintained in the Office of Premarket Approval.

Based on the information Aventis has presented to FDA, we have no further questions concerning corn silage and grains derived from the MS6 male sterile corn at this time. However, as you are aware, it is Aventis's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph. D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition